

200.1079US

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

SYNERGISTIC ANALGESIC COMBINATION  
OF OPIOID ANALGESIC AND  
CYCLOOXYGENASE-2 INHIBITOR

INFORMATION DISCLOSURE STATEMENT NO. 2

Assistant Commissioner for Patents  
Washington, D.C. 20231

June 7, 1999

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form relate to various compositions containing opioids and non-steroidal anti-inflammatory agents (commonly referred to as 'NSAIDS').

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: Jacqueline B. Vanden

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200.1079US

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

Clifford M. Davidson  
Reg. No. 32,728

Davidson, Davidson & Kappel, LLC  
1140 Avenue of the Americas, 15th Floor  
New York, New York 10036  
(212) 997-1028



200.1079US

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

**SYNERGISTIC ANALGESIC COMBINATION  
OF OPIOID ANALGESIC AND  
CYCLOOXYGENASE-2 INHIBITOR**

INFORMATION DISCLOSURE STATEMENT NO. 3

Assistant Commissioner for Patents  
Washington, D.C. 20231

June 7, 1999

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form relate to compounds described as being useful in the treatment of cyclooxygenase-2 mediated disease states. Reference 'AM' is cited for its discussion of COX-2 and COX-1 activity.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:

Jacqueline Reverder



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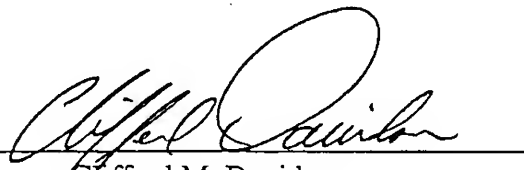
The Examiner's particular attention is directed to U.S. Patents No. 5,409,944 and 5,436,265, referenced on the enclosed PTO-1449 Form as 'AA,' and 'AB.' These patents describe, *inter alia*, compounds with cyclooxygenase-2 inhibitory properties in combination with "antitussives including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan." (See column 6, lines 33-35 of the '944 patent, and column 5, lines 48-50 of the '265 patent). The Examiner's attention is also directed to U.S. Patent No. 5,521,213, referenced on the enclosed PTO-1449 Form as 'AD.' This patent discloses, *inter alia*, "[a compound for treating cyclooxygenase-2 mediated diseases] and one or more ingredients such as another pain reliever including acetaminophen or phenacetin . . . an antitussive including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan . . . ." (See column 6, lines 7-15). A similar disclosure is also found in U.S. Patent No. 5,550,142 referenced on the enclosed PTO-1449 Form as 'AE,' at column 7, line 56 - column 8, line 5, U.S. Patent. 5,552,422, referenced on the enclosed PTO-1449 Form as 'AF,' at column 9, line 59 - column 10, line 7, U.S. Patent 5,604,253, referenced on the enclosed PTO-1449 Form as 'AG,' at column 10 line 66 - column 11, line 14, and U.S. patent 5,639,780, referenced on the enclosed PTO-1449 Form as 'AH,' at column 11, lines 36-51.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

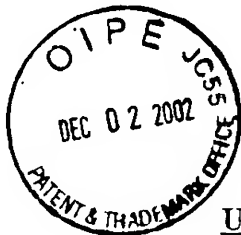
DAVIDSON, DAVIDSON & KAPPEL, LLC

  
Clifford M. Davidson  
Reg. No. 32,728

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New York, New York 10036  
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UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

**SYNERGISTIC ANALGESIC COMBINATION  
OF OPIOID ANALGESIC AND  
CYCLOOXYGENASE-2 INHIBITOR**

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

February 4, 2000

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form describe various COX-2 inhibitors, including 4-[4-(methylsulfonyl)phenyl]-3-phenyl-2(5H)-furanone (rofecoxib), the elected species set forth in the claims as amended.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on February 4, 2000.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: Ant J. Puro



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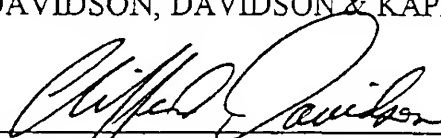
The references further describe the COX-2 inhibitors described therein in combination with "one or more ingredients such as another pain reliever including acetaminophen or phenacetin;...[and] an antitussive including codeine, hydrocodone, ...." (See column 8 of the '955 patent, and column 13 of the '374 patent). This is the same discussion included in other patents assigned to Merck Frosst Canada Inc., which was previously pointed out to the Examiner in the Information Disclosure Statement filed June 7, 1999. Oxycodone is not included in this discussion.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

  
\_\_\_\_\_  
Clifford M. Davidson  
Reg. No. 32,728

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1140 Avenue of the Americas, 15th Floor  
New York, New York 10036  
(212) 997-1028



UNITED STATES PATENT AND TRADEMARK OFFICE

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Re: Application of: BURCH et al.  
Serial No.: 09/154,354  
Group No.: 1627  
Filed: September 17, 1998  
For: SYNERGISTIC COMBINATION OF OPIOID ANALGESIC  
AND CYCLOOXYGENASE-2 INHIBITOR

Information Disclosure Statement under 37 C.F.R. § 1.97(b)(4) or alternatively under 37  
C.F.R. § 1.97(c)(1) with accompanying statement under 37 C.F.R. § 1.97(e)

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 26, 2001

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and pursuant to 37 C.F.R. § 1.97(b)(4), Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified application. It is believed that this Information Disclosure Statement is submitted before a first Office Action after the filing of a request for continued examination, therefore no fee is due.

In the event an Office Action has been mailed, this Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c)(1) with a statement under 37 C.F.R. § 1.97(e) declaring that each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify that the documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on September 26, 2001.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: J. Daniel Pantarat

It is pointed out to the Examiner that all of the cited references (AE through AO) were cited in the European Search Report from the corresponding European application. A copy of the search report is enclosed.

It is respectfully requested that the references cited on the accompanying PTO Form-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

In the event that it is determined that any additional fee is due, the Examiner is authorized to charge said fee to DAVIDSON, DAVIDSON & KAPPEL, LLC, Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

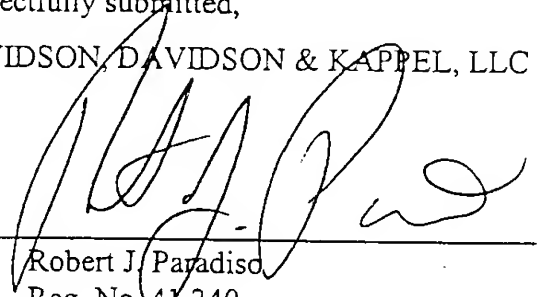
It is respectfully submitted that the pending claims are patentable over all the references made of record at this time.



Respectfully submitted,

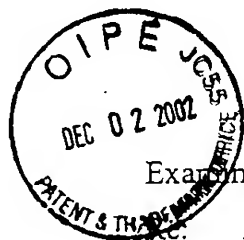
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940



UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

**ANALGESIC COMBINATION OF  
OXYCODONE AND ROFECOXIB**

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56

Box: ISSUE FEE

September 13, 2002

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. §§ 1.56 and 1.97, Applicants hereby make of record the following: Statement Of Ground and Particulars in Support of Opposition attached as Appendix A (20 pages); Claims of Australian Patent Application No. 742097 (93984/98) attached as Appendix B (5 pages); and Form PTO-1449 (2 pages) with copies of cited references pursuant to 37 C.F.R. § 1.98(d).

Attached as Appendix A is a Statement of Grounds and Particulars in Support of Opposition dated June 14, 2002, brought by Pharmacia Corporation at the Australian Patent Office opposing Australian Patent Application No. 742097 (93984/98), the corresponding Australian application of the present U.S. application.

Attached as Appendix B is a copy of the current claims of Australian Patent Application No. 742097 (93984/98), which claims the same priority as the present application.

References D1 to D7 (pages 2 to 4 of the statement of Appendix A), D9 to D16 (pages 5 to 7 of the statement of Appendix A) and D21 to D37 (pages 8 to 11 of the statement of Appendix A), correspond to references AA through BM of attached Form PTO-1449.

References D8 (page 5 of the statement of Appendix A) and D17 to D20 (page 7 to page 8 of the statement of Appendix A) are not listed on the accompanying Form PTO-1449 as these references have already been made of record in the present application. Specifically, reference D8 was cited as reference AA (on Form PTO-1449 labeled 1 of 1) and references D17, D18, D19, and D20 were cited as references BB, BD, BF, and BH, respectively, (on Form PTO-1499 labeled 2 of 2), in the Information Disclosure Statement filed June 7, 1999.

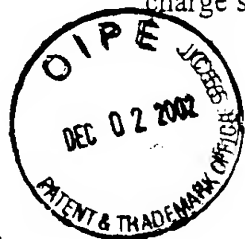
This Information Disclosure Statement and accompanying Form PTO-1449 are being filed after a notice of allowance under § 1.311 but before the payment of the issue fee in accordance with C.F.R. §§ 1.97(d) and 1.97(e).

In accordance with C.F.R. § 1.97(e)(2), it is stated that no item of information contained in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement.

A check in the amount of \$180.00 is enclosed to satisfy the fee requirement due under 1.17(p) for filing this Information Disclosure Statement.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If any of the listed references are missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

In the event any additional fee is due or overpayment made in connection with the filing of this Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.



Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: Bennett M. CELSA

Art Unit: 1627

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

ANALGESIC COMBINATION OF  
OXYCODONE AND ROFECOXIBSUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56

Box: ISSUE FEE

Assistant Commissioner for Patents  
Washington, D.C. 20231

October 1, 2002

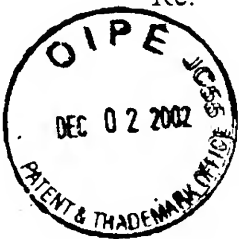
Sir:

Applicants hereby make of record the reference cited on the attached Form PTO-1449 and Appendix A, which is an amendment of the Statement of Grounds and Particulars in support of Opposition previously submitted in the Information Disclosure Statement filed September 13, 2002.

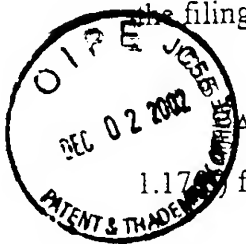
The Pharmacia Corporation, the Opponent of the corresponding Australian application requested amendment of their Statement to include a further document (referenced in the Statement as 38D). A marked-up copy of the Statement showing the amendments is attached as Appendix A, and the further document is cited as reference AA in the attached PTO-1449 Form.

This Information Disclosure Statement and accompanying Form PTO-1449 are being filed after a notice of allowance under §1.311 but before the payment of the issue fee in accordance with C.F.R. §§ 1.97(d) and 1.97(e).

In accordance with C.F.R. § 1.97(e)(2), it is stated that no item of information contained in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement

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was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement.



A check in the amount of \$180.00 is enclosed to satisfy the fee requirement due under 1.176 for filing this Information Disclosure Statement.

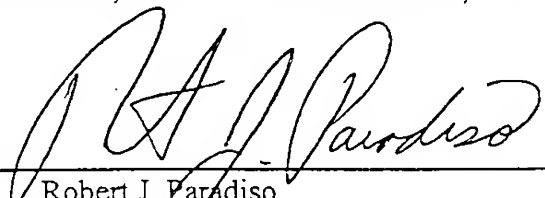
It is respectfully requested that the reference cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If this reference is found to be missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

In the event any additional fee is due or overpayment made in connection with the filing of this Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
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